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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/576,900	04/30/2007	Ralph Wirtz	2004P56021US	6097

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SIEMENS CORPORATION
INTELLECTUAL PROPERTY DEPARTMENT
170 WOOD AVENUE SOUTH
ISELIN, NJ 08830

EXAMINER

DAVIS, MINH TAM B

ART UNIT	PAPER NUMBER
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1642

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02/16/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/576,900	Applicant(s) WIRTZ ET AL.	
	Examiner MINH-TAM DAVIS	Art Unit 1642	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 02 November 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 11 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 11 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Applicant cancels claim 7, and adds new claim 11.

Accordingly, group F, claim 11, a method for diagnosis of breast cancer, using the combination of the nucleic acids of SEQ ID NO: 361, SEQ ID NO: 363, SEQ ID NO: 379 and SEQ ID NO:392, is examined in the instant application.

Withdrawn Rejection

The following rejections have been withdrawn in view of the amendment: 112, second paragraph, 112, first paragraph, written description, 112, first paragraph, enablement, item 2, concerning analog, derivative or allelic variants.

Claim Rejections - 35 USC § 112, First Paragraph, Enablement

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 11 is rejected under 35 U.S.C. 112, first paragraph, for lack of enablement for a method for detecting breast cancer, for reasons already of record in paper of 5/4/09.

The response asserts that the rejection is traversed in view of the amendment.

The response has been considered but is not found to be persuasive for the following reasons:

The specification discloses that differentially expressed cancer genes could be screened by methods known in the art (p.54, 110). The specification, however, does not have any data or objective evidence that the polynucleotides of SEQ ID NO: 361, SEQ ID NO: 363, SEQ ID NO: 379 and SEQ ID NO: 392 are differentially expressed in breast cancer tissue as compared to non-cancerous breast tissue, such that they can be used for diagnosis of breast cancer.

In the absence of objective evidence, one cannot predict whether SEQ ID NO: 361, SEQ ID NO: 363, SEQ ID NO: 379 and SEQ ID NO: 392 are differentially expressed in breast cancer tissues as compared to non-cancerous breast control tissues, such that they could be used for detecting breast cancer, because the level of expression of a polynucleotide in cancer tissue is not predictable, in view of the teaching of Stanton et al, Ihle et al, and Abbaszadegan et al, all of record.

Moreover, **a sample** as claimed encompasses any sample or tissue to which breast cancer cells have metastasized to. It is unpredictable that metastasized breast cancer cells still express the claimed sequences, because expression of a sequence could be lost during the progression toward metastasis, in view of the teaching of Russo et al, Kibel et al, Dong et al, all of record.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claim 11 is rejected under 35 U.S.C. 102(e) as being anticipated by Dai et al (US 7,171,311 B2, filed on 1/15/03), for reasons already of record in paper of 5/4/09.

The response asserts as follows:

Dai does not disclose or suggest the claimed method which detects at least four markers which include the recited sequences. Dai does not teach specified markers and one of ordinary skill in the art would not have been motivated to detect the particular markers as claimed.

The response has been considered but is not found to be persuasive for the following reasons:

Dai et al teach marker sets correlated with breast cancer, useful for diagnosis of breast cancer (column 20, first paragraph), and subsets of at least 5 markers, for distinguishing tumor types, such as ER+ and ER- patients (column 20, second paragraph). Dai et al teach that the target polynucleotides could be expressed RNA or amplified RNA (column 122, lines 15-20). SEQ ID NO:361, SEQ ID NO: 363, SEQ ID NO: 379, and SEQ ID NO: 392, respectively, of the claimed invention are 86.4% similar to SEQ ID NO:492, from nucleotide 62 to nucleotide 1480 of SEQ ID NO: 361, and 100% similar to SEQ ID NO: 484, SEQ ID NO: 485, and SEQ ID NO: 714, taught by Dai et al. The method taught by Dai et al would inherently detect SEQ ID NO:361, SEQ ID NO: 363, SEQ ID NO: 379, and SEQ ID NO: 392, due to their extensive homology.

Concerning motivation, this issue is moot here, since it is an inherent property to detect SEQ ID NO:361, SEQ ID NO: 363, SEQ ID NO: 379, and SEQ ID NO: 392.

Conclusion

No claims are allowed.

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a). A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to MINH-TAM DAVIS whose telephone number is 571-272-0830. The examiner can normally be reached on 9:00 AM-5:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, LARRY HELMS can be reached on 571-272-0832. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 1642

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MINH TAM DAVIS
January 29, 2010

/Larry R. Helms/

Supervisory Patent Examiner, Art Unit 1643